## § 32.12

it is introduced, method of introduction, initial concentration of the byproduct material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioisotopes in the product or material at the time of transfer; and

(c) Provides reasonable assurance that the concentrations of byproduct material at the time of transfer will not exceed the concentrations in §30.70 of this chapter, that reconcentration of the byproduct material in concentrations exceeding those in §30.70 is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

[30 FR 8192, June 26, 1965, as amended at 49 FR 19625, May 9, 1984; 72 FR 58487, Oct. 16, 2007]

## § 32.12 Same: Records and material transfer reports.

- (a) Each person licensed under §32.11 shall maintain records of transfer of byproduct material and file a report with the Director of the Office of Nuclear Material Safety and Safeguards by an appropriate method listed in §30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.
- (1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.
- (2) The report must indicate that the byproduct material is transferred for use under §30.14 of this chapter or equivalent regulations of an Agreement State.
  - (b) The report must identify the:
- (1) Type and quantity of each product or material into which byproduct material has been introduced during the reporting period;
- (2) Name and address of the person who owned or possessed the product or material, into which byproduct mate-

rial has been introduced, at the time of introduction;

- (3) The type and quantity of radionuclide introduced into each product or material; and
- (4) The initial concentrations of the radionuclide in the product or material at time of transfer of the byproduct material by the licensee.
- (c)(1) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after December 17, 2007, the licensee shall separately include data for transfers in prior years not previously reported to the Commission or to an Agreement State.
- (2) Licensees who permanently discontinue activities authorized by the license issued under §32.11 shall file a report for the current calendar year within 30 days after ceasing distribution
- (d) If no transfers of byproduct material have been made under §32.11 during the reporting period, the report must so indicate.
- (e) The licensee shall maintain the record of a transfer for one year after the transfer is included in a report to the Commission.

[72 FR 58487, Oct. 16, 2007, as amended at 73 FR 5719, Jan. 31, 2008; 73 FR 42673, July 23, 2008]

## § 32.13 Same: Prohibition of introduction.

No person may introduce byproduct material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under §30.14 of this chapter or equivalent regulations of an Agreement State, except in accordance with a license issued under §32.11.

[72 FR 58487, Oct. 16, 2007]

## § 32.14 Certain items containing byproduct material; requirements for license to apply or initially transfer.

An application for a specific license to apply byproduct material to, or to incorporate byproduct material into, the products specified in §30.15 of this chapter or to initially transfer for sale or distribution such products containing byproduct material for use pursuant to §30.15 of this chapter will be approved if: